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Donald M. Berwick
Administrator, Centers for Medicare & Medicaid Services
Attention: CMS- 3213-P
PO Box 8010
Baltimore, MD 21244-1850

Submitted electronically to http://www.regulations.gov

Re: **Medicare & Medicaid Programs; Influenza Vaccination Standards for Certain Participating Providers and Suppliers**
CMS-3213-P; RIN 0938-AP92 Fed.Reg. Vol. 76, No. 86/May 4, 2011.

Dear Administrator Berwick:

The American Nurses Association (ANA) welcomes the opportunity to offer comments on this proposed rule. The ANA is the only full-service professional organization representing the interests of the nation's 3.1 million registered nurses, the single largest group of health care professionals in the United States. We represent RNs in all roles and practice settings, through our state and constituent member nurses associations, and organizational affiliates. ANA advances the nursing profession by fostering high standards of nursing practice, promoting the rights of nurses in the workplace, projecting a positive and realistic view of nursing, and advocating before Congress and regulatory agencies on health care issues affecting nurses and the public. Our members include Advanced Practice Registered Nurses (APRNs) such as Nurse Practitioners (NPs), Clinical Nurse Specialists (CNSs), Certified Nurse Midwives (CNMs), and Certified Registered Nurse Anesthetists (CRNAs).

ANA concurs with the Centers for Medicare & Medicaid Services' proposed rule to require certain suppliers to offer all patients an annual influenza vaccine as a condition of participation (CoP). ANA is a strong supporter of influenza vaccination to promote health and prevent this vaccine-preventable disease, as demonstrated by our profession's commitment to disease prevention, and the ANA's *Bringing Immunity to Every Community* immunization initiative. Vaccination is an evidence-based strategy to reducing the health and financial burden of influenza, and CMS is in line with other health and policy objectives aimed at increasing the influenza vaccination rate for adults.

Registered nurses can independently administer influenza vaccine per standing orders, especially in public health settings or where a facility has implemented such a policy. ANA is pleased to see CMS acknowledge the role that standing orders play in helping Medicare and Medicaid providers meet this CoP. ANA encourages CMS to further promote the value of registered nurses providing influenza vaccine per standing orders as providers craft policies and procedures to meet this CoP.

Although ANA agrees in principle with this CoP, there are some externalities to this policy that CMS should consider in formulating the final rule.

Patient Record of Vaccination

Major gaps exist in the documentation of vaccine administration, particularly for adults. CMS should encourage providers to participate in state-based immunization registries by linking payment to participation. However, CMS must go one step further, as structural and administrative problems with the registries provide barriers to use. Many states severely limit which providers can enter or retrieve data from the registries, so vaccinations go unrecorded. Each state has its own listing of vaccinations and many have proprietary software, so the vaccine records do not follow a person from state to state. This results in a tremendous waste of time and money spent re-entering vaccination records, and over-vaccination when the records are not available. CMS can and should require states to support improved access for all vaccine providers for documentation and data retrieval.

Required Documentation

In §482.42 (c)(3)(iv)(B), CMS lists the required documentation of the reason the patient did not receive the vaccine. ANA encourages CMS to add "Prefers Other Vaccine Provider" or "Referred to Other Vaccine Provider". This will account for patients that intend to be vaccinated, but prefer to receive the vaccine from their primary care clinician or other clinic setting, such as at a work-based clinic. This suggested language should be duplicated in §485.635 (b)(3)(iv)(B), §491.9 (d)(3)(iv)(B), and §494.30 (d)(3)(iv)(B).

Vaccine Availability

In Part III "Adequacy of Vaccine Supply", CMS describes the unpredictable nature of vaccine supply. In the proposed rule §482.42(3), CMS states "Within its policies and procedures, the hospital must ensure the following, subject to the reasonable availability of vaccine…" ANA is concerned that CMS has not provided sufficient guidance on determining "*reasonable availability of vaccine*." CMS should consider stating that the provider or supplier must submit in writing the identified shortage of supply, and the steps it had taken to find alternative suppliers. CMS should also state it would allow exceptions to this CoP during a recognized shortage of vaccine supply. Vaccine supply is monitored by the Centers for Disease Control and Prevention's (CDC), and CMS must work closely with the National Centers for Respiratory and Infectious Diseases at CDC to identify when such shortages have been acknowledged. A key opportunity is

the ex-officio seat that CMS holds on the CDC's Advisory Committee on Immunization Practices (ACIP). CMS should continue to foster this important presence at the ACIP meetings, where a vaccine supply update is a routine agenda item. This change should be duplicated in §485.635 (b)(3), §491.9 (d)(3), and §494.30 (d)(3).

Implementation Date of Policy

CMS has proposed that this rule will be in effect for the 2011-2012 influenza season, and that states in the background section that a final rule will be published in "early fall." As much as ANA believes this is an important policy for CMS to pursue, this timeframe is unrealistic. Hospitals might have the necessary tools and resources to quickly implement this rule, however, the same may not true for providers that are not traditional vaccination sites, such as end-stage renal facilities. The time and process for enacting logistical elements of a vaccine program suitable to meet this rule cannot be underestimated. These include ordering vaccine, ensuring appropriate storage and handling protocols, altering patient record format to meet the documentation requirements of this rule, and implementing standing orders. ANA encourages CMS to publish this rule in the fall, but to not enforce the CoP until the 2012-2013 influenza season. This will allow for sufficient time for providers to properly design their policies, and to disseminate and operationalize standing orders.

Timing of this Rule

In §482.42 (c)(3)(ii), CMS has proposed that these CoPs would require a provider or supplier to offer influenza vaccine "as soon as the vaccine was available, on or after September 1 through the end of February". ANA encourages CMS to clarify the start date of this timeline. Discrepancies exist in the timing of vaccine shipments to vaccine providers, whether receiving vaccine directly from the manufacturer, or from a distributor (as in the case of most public programs). As a result, not all providers have all or even some of their vaccine order by September 1. Therefore, ANA suggests that the rule be changed to state that the provider or supplier should begin offering vaccine to patients "as soon as vaccine is available, but no later than September 30". CMS should also create exemptions to this start date in cases of vaccine supply disruption or shortage as recognized by the CDC, or in cases where the provider or supplier can prove an individual supply issue.

Additionally in regards to the timeline, ANA questions CMS selecting an end date of the "end of February". Influenza season typically peaks in February, however, seasonal activity is unpredictable, and widespread activity can occur as late as March or even April. Therefore, CDC often urges providers to continue offering influenza vaccination throughout the season, even into April. CMS should change its end-date to "April 1". This both accounts for the unpredictability of influenza activity, and offers a longer window of time to offer vaccine to patients that declined it on previous encounters. These changes to the timing should be duplicated in §485.635 (b)(3)(ii), §491.9 (d)(3)(ii), and §494.30 (d)(3)(ii).

We appreciate the opportunity to comment on this important rule. Immunizations are a vital public health intervention, and nurses are often the front-line educators and vaccinators in this country. ANA strongly believes that nurses, vaccinating through standing orders, will play a crucial role in making this policy succeed. If we can be of further assistance, or if you have any questions or comments, please feel free to contact Katie Brewer, MSN, RN, Senior Policy Analyst (katie.brewer@ana.org; 301-628-5043).

Sincerely,

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American Nurses Association

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